FDA Special 510(k) Notification

K050645

Cordis AMIIA .014" PTA Balloon Catheter

Attachment B:

510(k) Summary of Safety and Effectiveness

Submitter & Contact person:

Cordis Europa, N.V., a Johnson & Johnson Company
Harm Hovinga,
Oosteinde 8
NL-9300 LJ Roden,
The Netherlands
Tel: +31 (5050) 22479
Fax: +31 (5050) 22456
e-mail: hhovinga@crdnl.jnj.com

Date Prepared **March 11, 2005**

Trade Name **Cordis AMIIA™** Percutaneous Transluminal Angioplasty (PTA) Catheter

---

Classification Name & Device Classification

Classification Name:	**Percutaneous Catheter (21 CFR 870.1250)**
Classification:	**Class II**
FDA Classification Panel:	**Cardiovascular**
Product Code:	**LIT**

Predicate Device(s)

The predicate devices in this submission are the Cordis AVIATOR (510(k) #K013581) and the Cordis M3 PTA Balloon Catheters (510(k) #K003920, which have been determined substantial equivalent on November 28, 2001 and June 15, 2001 respectively.

FDA Special 510(k) Notification

Cordis AMIIA .014" PTA Balloon Catheter

Device description	The Cordis AMIIA PTA catheter has a shaft with a distal inflatable balloon. Two radiopaque marker bands indicate the dilatation section of the balloon and aid in balloon placement. The balloon dimensions are indicated on the hub ID band. The 142 cm catheter configuration has two proximal shaft markers at 90 cm and 100 cm from the distal tip to indicate the relative position of the catheter to the distal end of the guiding catheter. An additional marker is located at the distal port exit and aids in locating the exit location of the guide wire. A flushing needle is packaged with the catheter as an accessory for flushing the distal guide wire lumen prior tot use as indicated in the Instructions for Use
Intended Use	The **Cordis AMIIA** PTA catheter is intended to dilate stenoses in iliac, femoral, ilio-femoral, popliteal, infra popliteal and renal arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.
Safety and Performance Data	The safety and effectiveness of the subject Cordis AMIIA PTA Balloon Catheter has been demonstrated via data collected from non-clinical design verification tests and analyses. All materials used in this modified device have been tested according to ISO 10993-Part 1 and were found biocompatible.
Substantial Equivalence	In summary, the subject **Cordis AMIIA** PTA Catheter is, in our opinion, substantial equivalent to the predicate Cordis devices with respect to intended use, fundamental design and technology, sterility and operating principles.

FDA Special 510(k) Notification

Cordis AMIIA .014" PTA Balloon Catheter

Substantial Equivalence Statement

A statement of substantial equivalence to another product is required by 21 CFR 807.87 and relates only to whether the present product can be marketed without prior reclassification or clinical approval.
The present submission is therefore not related to the coverage of any patent and is not to be interpreted as an admission or used as evidence in a patent infringement lawsuit. As the commissioner of the FDA stated: "A determination of substantial equivalence under the Federal Food, Drug and Cosmetic Act related to the fact that the product can be lawfully marketed without pre-market approval or reclassification. The determination is not intended to have any bearing whatsoever on the resolution of patent infringement suits." 42 Federal Register 42, 50 et seq. (1977).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 1 2005

Cordis Europa N.V.
c/o Mr. Harm Hovinga
Senior Regulatory Affairs Associate
Oosteinde 8, 9301 LJ
Postbus 38, 9500 AA Roden
The Netherlands

Re: K050645
AMIIA .014" PTA Balloon Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II (Two)
Product Code: LIT
Dated: March 11, 2005
Received: March 14, 2005

Dear Mr. Hovinga:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4648. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

B Zuckerman for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

APPENDIX A:

Indications for Use

510(k) Number (if known): K050645

Device Name: Cordis AMIIA PTA Catheter

Indications For Use:

The Cordis AMIIA PTA catheter is intended to dilate stenoses in iliac, femoral, ilio-femoral, popliteal, infra popliteal and renal arteries and.for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.

Prescription Use ___X__ AND/OR Over-The-Counter Use ___
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K050645